

CLAIMS

1. A method of treating or alleviating a respiratory disorder which comprises administering an effective amount of the active ingredients formoterol, or a
5 pharmaceutically acceptable salt thereof, and fluticasone, or a pharmaceutically acceptable ester thereof, separately, sequentially or simultaneously, provided that the active ingredients comprise separate compositions.
2. A method according to claim 1 characterised in that the formoterol, or a
10 pharmaceutically acceptable salt thereof, and the fluticasone, or a pharmaceutically acceptable ester thereof, are administered separately or sequentially.
3. A method according to claim 2 characterised in that the formoterol, or a
15 pharmaceutically acceptable salt thereof, and the fluticasone, or a pharmaceutically acceptable ester thereof, are administered sequentially.
4. A method according to claim 3 characterised in that the method comprises the administration of fluticasone, or a pharmaceutically acceptable ester thereof,
20 followed by the sequential administration of formoterol, or a pharmaceutically acceptable salt thereof.
5. A method according to claim 2 characterised in that the formoterol, or a
pharmaceutically acceptable salt thereof, and fluticasone, or a pharmaceutically acceptable ester thereof, are delivered separately.
- 25 6. A method according to claim 1 characterised in that the formoterol, or a pharmaceutically acceptable salt thereof, and fluticasone, or a pharmaceutically acceptable ester thereof, are administered by inhalation.
- 30 7. A method according to claim 6 characterised in that the formoterol, or a pharmaceutically acceptable salt thereof, and the fluticasone, or a pharmaceutically

acceptable ester thereof, are administered by way of pressurised aerosols comprising a pharmaceutical composition in admixture with at least a suitable propellant.

8. A method according to claim 7 in which a surfactant is present.
- 5 9. A method according to claim 8 in which a surfactant is absent.
- 10 10. A method according to claim 9 characterised in that the surfactant is a mixture of surfactants.
- 11 11. A method according to claim 7 characterised in that the propellant, or mixture of propellants, is a non-CFC propellant.
- 12 12. A method according to claim 11 characterised in that the propellant, or mixture of propellants, is selected from hydrofluoroalkanes (HFA).
- 13 13. A method according to claim 12 characterised in that the propellant is HFA 134.
- 14 14. A method according to claim 12 characterised in that the propellant is HFA 227.
- 15 15. A method according to claim 12 characterised in that the propellant is a mixture of HFA 134 and HFA 227.
- 16 16. A method according to claim 6 characterised in that the formoterol, or a pharmaceutically acceptable salt thereof, and the fluticasone, or a pharmaceutically acceptable ester thereof, are administered by way of a dry powder inhaler.
- 17 17. A dry powder inhaler containing formoterol, or a pharmaceutically acceptable salt thereof, and fluticasone, or a pharmaceutically acceptable ester thereof, which

may be administered separately, sequentially or simultaneously, provided that they are administered as separate compositions.

18. A dry powder inhaler according to claim 15 comprising formoterol, or a
5 pharmaceutically acceptable salt thereof, and fluticasone, or a pharmaceutically
acceptable ester thereof, each in admixture with a pharmaceutically acceptable
adjuvant, diluent or carrier.
19. A dry powder inhaler according to claim 16 characterised in that the adjuvant,
10 diluent or carrier is selected from dextran, mannitol and lactose.
20. A dry powder inhaler according to claim 17 characterised in that the carrier is
lactose.
- 15 21. A dry powder inhaler according to claim 17 characterised in that the dry
powder inhaler is selected from those described in PCT/GB 00/04623.
22. A dry powder inhaler according to claim 17 characterised in that the dry
powder inhaler is selected from those described in PCT/GB 00/03377.
- 20 23. A method according to claim 1 characterised in that the formoterol, or a
pharmaceutically acceptable salt thereof, and fluticasone, or a pharmaceutically
acceptable ester thereof, are administered by way of a nebuliser comprising a solution
or a suspension of formoterol, or a pharmaceutically acceptable salt thereof, and
25 fluticasone, or a pharmaceutically acceptable ester thereof.
24. A method according to Claim 1 characterised in that a the amount of
formoterol, or a pharmaceutically acceptable salt thereof, administered to a patient is
from 20 to 500 µg and the amount of fluticasone, or a pharmaceutically acceptable
30 ester thereof, administered to a patient is from 3 to 50 µg, once or twice daily.

25. A method according to claim 1 characterised in that the respiratory disorder is COPD.
26. A method according to Claim 1 characterised in that the pharmaceutically acceptable salt of formoterol, is selected from an acid addition salts; hydrochloride, hydrobromide, sulphate, phosphate, maleate, tartrate, citrate, benzoate, 4-methoxybenzoate, 2- or 4-hydroxybenzoate, 4-chlorobenzoate, p-toluenesulphonate, methanesulphonate, ascorbate, salicylate, acetate, fumarate, succinate, lactate, glutarate, gluconate, hydroxynaphthalenecarboxylate and oleate.
27. A method according to claim 26 characterised in that the pharmaceutically acceptable salt of formoterol, is the fumarate salt.
28. A method according to claim 1 characterised in that the pharmaceutically acceptable ester of fluticasone, is the propionate ester.
29. A method of attaining improved glucocorticoid receptor translocation into the nucleus by the administration of a therapeutically effective amount of a β_2 agonist and a steroid in therapeutically effective amounts wherein the method provides an improvement of at least 20% over prior art β_2 agonist and steroid combination therapies.
30. The use of formoterol, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for use in the method according to claim 1.
31. The use of fluticasone, or a pharmaceutically acceptable ester thereof, in the manufacture of a medicament for use in the method according to claim 1.
32. The use of formoterol, or a pharmaceutically acceptable salt thereof, and fluticasone, or a pharmaceutically acceptable ester thereof, as active ingredients in the manufacture of a medicament to be administered separately, sequentially or

simultaneously, provided that the active ingredients comprise separate compositions for the treatment or alleviation of a respiratory disorder.

33. The use of a glucocorticoid in the manufacture of a medicament with improved β_2 receptor expression.

34. A method according to Claim 1 characterised in that the ratio of formoterol, or a pharmaceutically acceptable salt thereof, to fluticasone, or a pharmaceutically acceptable ester thereof, is in the range 1 : 0.4 to 1 : 167.

35. A method or an inhaler substantially as described with reference to the accompanying examples.